

## Missouri Department of Health and Senior Services'

## **BUREAU OF NARCOTICS & DANGEROUS DRUGS**

January 2010 (Updated February 2010)

www.dhss.mo.gov/BNDD

# <u>Limited Changes to Schedule</u> <u>II Prescriptions</u>

Pharmacy employees may make certain changes to controlled substance prescriptions for drugs on schedules III, IV and V. After contacting the prescriber, the pharmacy may change the following:

- Date
- Patient address
- Drug strength
- Dosage form
- Drug quantity
- Directions for use
- Prescriber address
- Prescriber DEA number
- Status as a hospice patient

The three items a pharmacy cannot change is NAME—NAME—NAME; which is the:

- Name of the patient;
- Name of the drug;
- Name of the prescribing practitioner, whether by adding or changing the name.

In December 2008, the DEA enacted a new regulation regarding how multiple Schedule II prescriptions could be issued with "Do not fill until\_\_\_\_" written on the prescriptions. This new rule also states that pharmacies cannot make essential changes to Schedule II prescriptions. Changes cannot be made to:

- Drug name;
- Strength;
- Form:
- Quantity;
- Name of patient;
- Name of prescriber

# Methadone For Infants With Opioid Withdrawal

Patients seeking treatment for opiate addiction may enter Narcotic Treatment Programs (NTPs) to receive methadone. A facility must be licensed and specifically registered with BNDD and the DEA as a Narcotic Treatment Program.

In treating addiction, the methadone must be administered directly to the patient and it cannot be prescribed or dispensed to the patient for later use.

At times, however, infants and children suffering opioid withdrawal need to receive methadone. Those circumstances usually involve children being discharged from an acute care hospital.

But Narcotic Treatment Programs may not routinely accept children. And it is not cost effective to require a child to stay in a hospital and accumulate in-patient hospital expenses, just to receive an administration of methadone.

In such cases, a physician treating a child for opioid withdrawal may issue a prescription for methadone. In 2001, the Federal Interagency Narcotic Treatment Policy Review Board (INTPRB) decided that the use of opioids for infants and children suffering withdrawal does not fall under the Narcotic Addict Treatment Act (NATA) and is not subject to the same rules and regulations affiliated with that Act.

In response to an increased number of hospitals needing to discharge these children, the INTRB stressed to practitioners that these infants are not considered addicts.

The board emphasized that a physician treating IAS or NAS was free to write prescriptions for any opioid, including methadone, that would be appropriate to treat IAS or NAS based on clinical judgment, existing standards of practice and the patient's response to therapy.

Physicians should make special efforts to document the prescriptions with additional information so pharmacies are aware the prescription is for a child with IAS or NAS.

### Coroners Should Not Seize Drugs from Practitioners

The BNDD and law enforcement agencies have received complaints recently where coroners have been seizing the controlled substance prescriptions of deceased patients. In these cases, the patients were in a long-term care facility or hospice where the death was witnessed by treating practitioners and no foul play was suspected. The coroner attempted to seize the drugs so the drugs could be donated to another patient as a cost saving measure. BNDD provides the following information to health care practitioners in these situations:

- 1. The coroner has certain powers to seize a scene and evidence where suspicious circumstances exist. The coroner is required to call law enforcement to the scene where law enforcement should conduct the investigation. Any evidence seized at the scene is required to be handed over to the police or prosecuting attorney.
- 2. The seizing of a scene and drugs should occur when there is indication of a possible crime. This seizing should not take place when a patient dies under normal circumstances in the care of licensed facility and in the presence of licensed health care practitioners.
- 3. State and federal laws prohibit controlled substances being taken from one patient and shared or donated to another. The transferring of controlled substances is strictly prohibited.
- 4. When a patient dies, the medical practitioners should inventory the drugs and then have them destroyed in front of a witness. The latest FDA standards call for the controlled substances to be flushed down a toilet and not merely discarded in the trash.
- 5. Coroners seizing controlled substances are required to complete a report and turn evidence over to the proper authorities and maintain a chain of custody.

# How Patients Should Destroy Unwanted Medications

The BNDD receives numerous inquiries regarding how unwanted medications should be destroyed. DEA registrants with controlled substances in their practices must dispose of unwanted controlled drugs pursuant to State Regulation 19 CSR 30-1.078. This regulation is available on our BNDD website at <a href="https://www.dhss.mo.gov/BNDD">www.dhss.mo.gov/BNDD</a>. Click on the link to regulations.

Patients have more latitude and may destroy unwanted household medications by mixing them with garbage and discarding them in their household trash or if they are controlled substances the FDA has instructed patients to flush unwanted controlled substances down the toilet. An educational handout that is prepared specifically for patients is available on the BNDD website under the link to publications.





### **Recent DEA Actions**

The DEA has scheduled some new controlled substances and the agency is in the process of scheduling others. Here is the status as of January 1, 2010.

#### **Scheduled Substances:**

- Lacosamide to Schedule 5 on June 22, 2009
- ❖ Tapentadol to Schedule 2 on June 22, 2009
- ❖ Fospropofol to Schedule 4 on November 5, 2009

#### Publicly Filed—Not Final Yet:

- ❖ 5-MeO-DMT to Schedule 1
- Carisoprodol (Soma<sup>TM</sup>) to Schedule 4
- Three anabolic steroids to Schedule 3
  - Boldione;
  - Desoxymethyltestosterone;
  - 19-nor-4,9(1)-androstadienedione

Also be sure to visit the newly remodeled DEA website at www.deadiversion.usdoj.gov

## What is the BNDD Working On?

The BNDD is working on several projects scheduled to be completed during the first quarter of 2010. The BNDD will be preparing information and statistical reports for budget hearings and also drafting fiscal notes and reviews for legislation that is filed affecting controlled substances.

- 1. The bureau is working to update the list of controlled substances;
- 2. Although a complete list of all controlled substances can be viewed at the DEA website, the BNDD has added a similar list on its state web page since certain drugs are scheduled differently in Missouri;
- 3. The BNDD provides a link to controlled substance statutes and also controlled substance regulations. The bureau has drafted a concordance that indexes regulatory requirements and their citations. Viewers can look at a list of topics and requirements and see the accompanying citation so they may find the exact requirement in the statute. An example would be the requirements for an annual inventory of controlled substances, which is found in Section 195.050.6, RSMo and in 19 CSR 30-1.042(1)(2)(3).
- 4. The bureau continues to work toward establishing a class on controlled substances record keeping and security that can be offered online where practitioners can receive continuing education credits.



# Get a New Calendar

This time of year, everyone is getting a new calendar and penciling in their important dates. Licensed practitioners know that it's a good idea to have a separate regulatory calendar that you check each month. This calendar should be placed in a conspicuous location to remind staff of license expiration dates, renewal reminders, registration expiration dates, city licenses due and insurance requirements.

## <u>History of Statutes Being</u> Amended

Original statutes were enacted in 1939.

	Statutes Amended			
1945	1971	1987	1996	2006
1953	1975	1988	1997	2008
1957	1978	1989	2001	2009
1959	1982	1993	2002	
1965	1985	1994	2005	

## **Physicians Can Treat Relatives**

One of the most common questions received at the bureau is whether physicians have the authority to treat and prescribe for their own family members. In the state of Missouri, physicians may treat their own family members, but they are required to maintain a full chart and treat relatives as they would any other patients. They are required to have a chart with treatment documented as laid out in Section 334.097.1, RSMo. This law requires documentation of exams, dates seen, patient history, treatment plans and medications authorized.

## B.N.D.D. History

1939—1974	Department of Public Health & Welfare Division of Health			
	Bureau of Food and Drug Inspection			
1974—1985	Department of Social Services			
	Division of Health			
	Bureau of Narcotics and Dangerous Drugs			
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1985—1995	Department of Health			
	Division of Health Resources			
	Bureau of Narcotics and Dangerous Drugs			
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1995—May 2001 Department of Health				
1,700 1,1mg 20	Division of Health Standards and Licensure			
	Bureau of Narcotics and Dangerous Drugs			
3.6 A004 FF				
May 2001—To	oday Department of Health and Senior Services			
	Division of Regulation and Licensure			
	Section for Health Standards and			

Licensure

Bureau of Narcotics and Dangerous Drugs